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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
The assigned 510(k) number is: K061150.

1. Submitted by:	Sysmex America, Inc. One Nelson C. White Parkway Mundelein, IL 60060 Phone: (847) 996-4675; FAX: (847) 996-4655 Contact person: Nina Gamperling Date prepared: April 24, 2006
2. Name of Device:	Trade or proprietary name: Sysmex® Automated Hematology Analyzer, XT- Series Common name: Automated Hematology Analyzer. Classification name: Sysmex® XT-Series, Automated Hematology, an Automated Differential Cell Counter (21 CFR 864.5220) is a Class II medical device.
3. Predicate Method:	The Sysmex® XT- Series Body Fluid Application claims substantial equivalence to the Sysmex XE-Series Body Fluid Application
4. Device Description:	The XT-Series is an automated hematology analyzer previously cleared by the FDA. The combination of side scatter, forward scatter, and fluorescent intensity of nucleated cells gives an image of each cell detected in the specimen.
5. Intended Use:	The Sysmex® XT-Series Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter for *in vitro* diagnostic use in clinical laboratories. The XT- Series Body Fluid Application adds a quantitative, automated procedure for analyzing body fluids such as cerebrospinal fluid, serous fluid and synovial fluid to the XT-Series, providing enumeration of the WBCs and the RBCs.
6. Substantial equivalence-similarities and differences	The following table compares the XT- Series Body Fluid Application with the predicate method, XE-Series Body Fluid Application.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(continued)

Comparison to Predicate Method

	Predicate Method	**New Instrument Method**
	XE-2100 Series Body Fluid Application	**XT- Series Body Fluid Application**
Intended Use	To provide a quantitative determination of blood cells in body fluids such as cerebrospinal fluid, serous fluid and synovial fluid.	Same as predicate method
Methodology	Cell count is performed on an automated hematology analyzer.	Same as predicate method
Reagents	Cellpack, Sulfolyser, Stromatolyser-FB, Stromatolyser-4DL, Stromatolyser-4DS, Stromatolyser, NR, Stromatolyser-IM, Cellsheath Ret-Search II	Cellpack, Sulfolyser, Stromatolyser-FB, Stromatolyser-4DL, Stromatolyser-4DS, Ret-Search II
Specimen Type	Body Fluids such as Cerebrospinal fluid, Serous fluid, Synovial fluid	Same as predicate method
Accuracy	Performance was established in the previous 510(k) submission.	Comparison to the XE-2100 Series Body Fluid Application demonstrated excellent correlation.

7. Clinical Performance Data:	Studies were performed to evaluate the equivalency of the automated method to the predicate method. Results indicated equivalent performance.
8. Conclusions:	The performance data demonstrated substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Nina M. Gamperling, MBA, MT (ASCP), RAC
Manager, Regulatory Affairs
Sysmex Corporation of America
One Nelson C. White Parkway
Mundelein, Illinois 60060

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Re: k061150
Trade/Device Name: Sysmex® XT-Series, Automated Hematology Analyzer, Body Fluid Application
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: II
Product Code: GKZ
Dated: April 24, 2006
Received: April 25, 2006

Dear Ms. Gamperling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K061150

Device Name: Sysmex® XT- Series, Automated Hematology Analyzer

Indications For Use:

The Sysmex® XT-Series Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter for *in vitro* diagnostic use in clinical laboratories. The XT- Series Body Fluid Application adds a quantitative, automated procedure for analyzing body fluids such as cerebrospinal fluid, serous fluid and synovial fluid to the XT- Series, providing enumeration of the WBCs and the RBCs.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety